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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,018	04/24/2002	Dorit Arad	10365/07406	4459

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EXAMINER

ZEMAN, MARY K

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9/17

Office Action Summary	Application No. 10/031,018	Applicant(s) ARAD ET AL	
	Examiner Mary K Zeman	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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Election/Restriction

Claims 1-24 are pending in this application.

Lack of Unity

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

With respect to unity of invention PCT Rule 13.1 states:

The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

Additionally, PCT Rule 13.2 states:

Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

With regard to the application of PCT Rule 13, 37 CFR §1.475 concerning unity of invention states:

- (a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
- (b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:
 - (1) A product and a process specially adapted for the manufacture of said product; or
 - (2) A product and a process of use of said product; or
 - (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
 - (4) A process and an apparatus or means specifically designed for carrying out the said process; or
 - (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.
- (c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.
- (d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).
- (e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

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Group I, claim(s) 1-6 and 24 drawn to a process for the design of anti-tumor compositions.

Group II, claim(s) 7-11, drawn to a method for the design of a paclitaxel alternative composition.

Group III, claim(s) 12 and 17-23-in-part, drawn to a first chemical composition- SPECIES ELECTION REQUIRED.

Group IV, claim(s) 13 and 17-23-in-part, drawn to a second chemical composition- SPECIES ELECTION REQUIRED

Group V, claim(s) 14 and 17-23-in-part drawn to a third chemical composition- SPECIES ELECTION REQUIRED.

Group VI, claim(s) 15 and 17-23-in-part, drawn to a fourth chemical composition- SPECIES ELECTION REQUIRED.

Group VII, claim(s) 16 and 17-23-in-part, drawn to a fifth chemical composition- SPECIES ELECTION REQUIRED.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The chemical compositions of Groups III-VII are not a novel contribution over the art. WANG et al. (1999) Organic Letters, Vol. 1 No. 1 p 43-46, cited in the international search report, discloses paclitaxel alternative compositions and derivatives that meet the requirements of the claims. (See page 44). As such the chemicals themselves are not a novel contribution over the art, and are not a special technical feature linking all the groups. The methods of Groups I and II are methods of design, and are not limited to any particular structure, such that no particular chemical links all the groups. The two methods do not share a special technical feature, as they are differing methods having differing steps and goals. Therefore, neither the chemicals of Groups II-VII nor the methods of Groups I-II set forth a special technical feature linking all the claims as defined in PCT Rule 13.2.

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Group I, claims 1-6 and 24 share the inventive concept of being drawn to the method of designing anti-tumor compositions using 3-dimensional modeling, based on a known anti-tumor composition.

Group II, claims 7-11, share the inventive concept of being drawn to the method of designing a paclitaxel alternative composition using particular atomic measurements and comparisons.

Group III, claims 12 and 17-23-in-part, share the inventive concept of being drawn to the first chemical composition having variables of R1-R6 and X.

Group IV, claim 13 and 17-23-in-part, share the inventive concept of being drawn to the second chemical composition having variables of R1-R6 and X.

Group V, claim 14 and 17-23-in-part, share the inventive concept of being drawn to the third chemical composition having variables of R1-R6 and X.

Group VI, claim 15 and 17-23-in-part, share the inventive concept of being drawn to the fourth chemical composition having variables of R1-R6 and X.

Group VII, claim 16, and 17-23-in-part, share the inventive concept of being drawn to the fifth chemical composition having variables of R1-R6 and X.

This application contains claims directed to the following patentably distinct species of the claimed invention of Groups III-VII: Each chemical compound falling within each group is a differing species. Each chemical is a different chemical entity, having a differing structure. Applicant is required to elect ONE constituent for EACH variable in the recited structure. For example, if Group III is elected, a constituent for each of R1, R2, R3, R4, R5, R6 and X must be specifically elected and recited.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Each of the chemicals listed in claims 12-16 are separate and distinct, as the structures are not a novel contribution over the art, as identified above. WANG (1999) discloses compositions meeting the limitations of the claims.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 12-16 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).


A fully responsive reply will comprise the Group elected, a particular species elected if applicable, and all claims reading upon the elected group and/or species.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P Woodward can be reached on (571) 272 0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. **Should you have questions on the contents of the electronic file wrapper, or on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).**


MARY K. ZEMAN
PRIMARY EXAMINER
AC 1631
6/16/04